Twenty-Seven Years of Continuous Treatment of Multiple Sclerosis With Glatiramer Acetate: Long-Term Efficacy Results of the US Open-Label Extension Study

Short title for mobile app: Long-Term Efficacy in GALA 27-Year Study (40 of 45 characters)

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Introduction: Glatiramer acetate (GA) is the only treatment for relapsing multiple sclerosis (RMS) that has been prospectively studied for more than two decades in a continuously monitored, long-term trial. We report the 27-year efficacy results of the open-label extension (OLE) of the US pivotal trial of branded GA.

Objective: To assess the long-term effectiveness of early start (ES) and delayed start (DS) GA treatment in patients with RMS.

Methods: At the end of the up-to-36-month, randomized, placebo-controlled trial, patients could enter an OLE phase: those receiving GA continued treatment (ES), and those receiving placebo switched to GA (DS).

Results: Of 251 randomized patients, 208 entered the OLE; 52 completed the study. At randomization, mean age and duration of disease were 34.4 and 7.0 years, respectively. Mean study duration and duration of GA exposure were 13.6 and 12.3 years, respectively. A total of 29.5% of patients had >20 years' GA exposure. Over the entire study, the baseline-adjusted annualized relapse rate was 0.33 for ES and 0.41 for DS (RR: 0.79; 95% CI: 0.586–1.069; *P*=0.13). Baseline-adjusted percentage of patients without relapse over the study period was 20.4% for ES and 13.3% for DS (OR: 1.54; 95% CI: 0.748–3.155; *P*=0.24). ES treatment prolonged the time to 6-month confirmed disability progression (CDP) (median 9.8 years)

compared with DS (median 6.7 years) (HR 0.76; 95% CI: 0.544–1.061; *P*=0.11). The proportion of patients without 6-month CDP was 48.0% for ES and 37.3% for DS. Baseline-adjusted percentage of NEDA2 (no relapse, no 6-month CDP) patients over the study period was 12.7% for ES and 5.9% for DS (OR: 2.16; 95% CI: 0.848–5.482; *P*=0.11).

Conclusions: Results from the 27-year OLE study reinforce the effective use of branded GA in patients with RMS. ES patients showed nominally lower clinical disease activity compared with DS patients.

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